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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/470,009	12/22/1999	JEONG S. LEE	003764.P006	5656
24201	7590	10/06/2004	EXAMINER	
FULWIDER PATTON LEE & UTECHT, LLP HOWARD HUGHES CENTER 6060 CENTER DRIVE TENTH FLOOR LOS ANGELES, CA 90045			LAM, ANN Y	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/470,009

**Applicant(s)**

LEE ET AL.

**Examiner**

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-19, 21-23, 25, 26, 51, 53, 56-60, 64 and 65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-19, 21-23, 25, 26, 51, 53, 56-60, 64 and 65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12, 58, 60 and 65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is vague and indefinite since it recites acronyms (PEEK, PPS, PEI and PI.)

Claim 58 recites the limitation "adapted to" and vague and indefinite since it is not clear as to how the inner tubular member has been modified to receive the guidewire (the indefiniteness can be overcome by deleting "adapted to".)

Likewise, claims 60 and 65 recite "adapted to" language and is indefinite for similar reasons.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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1. Claims 11, 13-15, 17-19, 21-26, 50, 51, 56-60, 65-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard, 5,242,396, in view of Berenstein et al., 5,895,378, and further in view of Crowley et al., 6,004,279.

Evard discloses the invention substantially as claimed.

More specifically, as to claim 11, Evard discloses a mandrel (26) having a solid core comprised of a variable stiffness, non-metal material (i.e., plastic, see column 3, lines 38-42, and column 4, lines 28-30) said mandrel uniformly tapered from a proximal section to a distal section (see column 3, lines 38-42, and Figure 1), and said mandrel adapted to reinforce a catheter (see Figure 1.)

As to claim 19, Evard discloses an outer member (17); a hollow inner member (14) extending through said outer member; an outer lumen (18) between said inner and outer members; and a mandrel extending through said outer lumen, said mandrel comprised of a variable stiffness material, said mandrel uniformly tapered, see column 3, lines 38-42, from a proximal section to a distal section and said mandrel is adapted to reinforce said catheter (see Figure 1.)

As to claims 13, 21 and 56, a diameter of said proximal section is larger than a diameter of said distal section of said uniformly tapered mandrel, i.e., a diameter tapering from the proximal end of the mandrel to the distal end of the mandrel, see Figure 1.

As to claims 14 and 22, the catheter comprises an inflatable member (12, 22 and 23) secured to the catheter shaft, wherein said distal section of said mandrel (26)

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extends to a location along the length of the catheter located in the inflatable member, see Figure 1.

As to claims 15 and 23, said distal section of said mandrel (26) extends to a location proximal to the inflatable member (see figure 1.)

As to claims 16, 24 and 45, said mandrel (26) is capable of being formed by annealing to induce a higher crystallinity such that said proximal section is stiffer than said distal section.

As to claims 17 and 25, said mandrel (26) is capable of being formed by necking at high temperatures such that said proximal section is stiffer than said distal section.

As to claims 18, 26 and 51 said mandrel (26) is capable of being formed by taper extruding such that said proximal section is stiffer than said distal section.

As to claims 57, 59, and 65, the mandrel is fixed to the catheter shaft (see column 3, lines 38-39.)

As to claims 58, 60, 64, and 66, an inner tubular member (14) is disposed near the mandrel, wherein the inner tubular member is adapted to receive a guidewire (see column 3, lines 21-26.) Also, as to claim 64, the mandrel is formed of a polymer compatible with a polymer forming the catheter shaft (col. 4, lines 28-30.)

Evard discloses that the tapering of the mandrel provides flexibility in the distal portion (col 2. lines 65-68.) However, Evard does not disclose that the proximal section has a first crystallinity and the distal section has a second crystallinity lower than the proximal section first crystallinity such that the proximal section is stiffer.

Berenstein teaches that where a catheter is formed from PVC or a polyurethane, the catheter is provided with added flexibility where the catheter is annealed (column 5, line 58 – column 6, line 4.)

Crowley further teaches a guidewire wherein the distal portions are annealed progressively to cause the distal portions to be more flexible than proximal portions (column 2, lines 6-10.) (Examiner emphasizes that a guidewire is equivalent to or at least comparable to a mandrel since a guidewire provides substantially the same function as a mandrel in that both provide rigidity to a catheter to enable a catheter to be inserted in a patient.)

In short, Evard teaches a mandrel formed from a plastic material (column 4, line 30), wherein it is desirable for the distal end portion to be flexible (col. 2, lines 65-68.) Berenstein teaches that PVC or polyurethane (i.e., plastic materials) can be annealed to provide flexibility. Crowley teaches that distal portions of a guidewire can be progressively annealed in order to provide gradual flexibility to a guidewire as would be desirable for insertion into a patient. It would have been obvious to progressively anneal the Evard plastic mandrel, as taught by Crowley in view of Berenstein, in order to provide gradual flexibility to a mandrel as would be desirable for insertion into a patient as taught by Crowley. This added flexibility is also taught to be desirable in Evard. (Annealing provides the proximal section with a higher crystallinity than the distal section.)

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2. Claims 12, 16, 53 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over over Evard, 5,242,396, in view of Crowley et al., 6,004,279, further in view of Berenstein et al., 5,895,378, and further in view of Lee et al., 6,733,486.

The invention as claimed is substantially disclosed by Evard in view of Berenstein and further in view of Crowley (see above.) More specifically, Evard teaches that the mandrel can be made of suitable high strength plastic material (col. 4, lines 28-30.) However, as to claims 12 and 53, Evard does not specifically disclose that the plastic material is PEEK (or polyetheretherketone.)

Lee discloses a mandrel (30) to reinforce a balloon catheter (10) (col. 4, lines 14-16.) Lee also discloses that the mandrel is made from pseudo-elastic or shape-memory materials including polymers such as PEEK (col. 4, lines 30-33).

It would have been obvious to one of ordinary skill in the art to use PEEK as the plastic material to form the Evard mandrel since Lee teaches that PEEK can be used to form a mandrel for reinforcing a balloon catheter since it is pseudo-elastic and has shape-memory characteristics.

As to claims 16 and 64, Evard discloses that the mandrel is fixed within the annular lumen (18) but does not specifically disclose that the mandrel is fusion bonded to the catheter shaft.

Lee teaches that mandrel (84) is bonded to the tubular member (70) and (62), in an embodiment that does not have sidewall (80), (embodiment not shown, but is similar to figure 11 except without sidewall 80.) Lee teaches that the mandrel can be bonded by conventional means of attachment (col. 7, lines 11-12.) Lee also discloses on

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column 4, lines 45-47, that the catheter components can be bonded together by heat fusion, adhesive, or by other conventional means.

It would have been obvious to one of ordinary skill in the art to fix the Evard mandrel to the catheter shaft by fusion bonding the mandrel to the shaft as taught by Lee as a conventional means of attachment.

### ***Response to Arguments***

Applicant's arguments filed August 12, 2004 have been fully considered but they are not persuasive.

Applicant argues on page 9 that Crowley and Berenstein teach an annealed section which is made more flexible, in contrast to Applicant's claim which requires that the mandrel has an annealed proximal section which is less flexible than the distal section. Applicant further states that annealing the distal section of the mandrel to increase its flexibility does not disclose an embodiment having an annealed proximal section which is less flexible than or has a higher crystallinity than the distal section.

In response, Examiner points to Crowley column 4, lines 62-65, which states that "the flexibility of medical guidewire 10 may be varied by progressively annealing either a portion, e.g., distal tubular portion 24, or the entire length of medical guidewire 10." Examiner emphasizes that Crowley teaches *varying* the flexibility by *progressively* annealing a portion of the guidewire or the entire guidewire (which is equivalent or comparable to a mandrel.) Progressively annealing the guidewire to vary the flexibility



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of, for example the entire guidewire, would mean that the proximal section is less flexible than, or has a higher crystallinity than, the distal section.

Applicant also made arguments on page 9 with respect to claims 16 and 64, but the arguments are now moot in view of the new grounds of rejection based on the amendments to claims 16 and 64.

Applicant also made arguments on page 10 with respect to the rejection based on Shank, but the arguments are now moot in view of the withdrawal of the rejection under Shank.

Applicant also made arguments on page 10 with respect to the rejection based on Hibbs, but the arguments are now moot in view of the withdrawal of the rejection under Hibbs.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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